JUL 2 1 2000 K001390

Biosense Webster
a Johnson-Johnson company

Einstein Building, Etgar St., New Industrial Zone,
POB 2009, Tirat HaCarmel 39120 ISRAEL
Tel: +972-4-8576057 Fax: +972-4-8571071
e-mail: sstolars@bwiil.jnj.il

Abbreviated 510(k) Summary for the Biosense Webster Patient Cable and Leadwires

1. Establishment information

Submitter

Biosense Webster, Inc.
3333 Diamond Canyon Rd.
Diamond Bar, CA 91765
USA
Phone: 800-729-9010, ext. 8593
Fax: 909-468-3781
Registration number: 2029046 and 2020638

Contact person

Maria D. Ochoa
Regulatory Affairs Specialist

Manufacturer

Biosense Webster (Israel) Ltd.
POB 2009
Tirat HaCarmel, 39120
Israel

2. General Device Information

Proprietary device name:	Biosense Webster Patient Cable and Leadwires
Classification name:	Patient transducer and electrode cable (including connector), 21 CFR 870.2900
Common device name:	Patient Cable and Leadwires
Classification	Class II

3. Substantial Equivalence

The Biosense Webster Patient Cable and Leadwires are substantially equivalent to the CONMED Patient Cable and Leadwires, which are legally marketed under 510(k) K933649.

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4. Device Description

The Biosense Webster cable and leadwires system are a reusable electrode cable system used to transmit signals from patient electrodes to the CARTO and NOGA recording systems.

The cable system is composed of a trunk cable, and two sets of leadwires.

The trunk is defibrillation proof and contains a 10-pin, double recessed connector to accommodate the leadwires.

There are two types of leadwires: standard and x-ray translucent. Each leadwire terminates in a double socket connector on one side, and a spring loaded grabber, for connection to the patient electrode, on the other side.

5. Intended Use

The Biosense Webster Patient Cable and Leadwires System (consisting of a cable and leadwires) is intended to connect patient electrodes, placed on the patient body surface, to the CARTO and NOGA recording and mapping systems.

6. Technological comparison to legally marketed predicate device

The Biosense Webster Patient Cable and Leadwires System is comparable in electrical and mechanical characteristics to the CONMED patient cable and leadwires system (K933649).

The Biosense Webster Patient Cable and Leadwires System complies with ANSI/AAMI EC53-1995 and with 21 CFR 898, and all requirements for reusable cables have been met.

7. Conclusion

The Biosense Webster Patient Cable and Leadwires System is substantially equivalent to the predicate device in construction, materials, and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2000

Ms. Maria D. Ochoa
Regulatory Affairs
Biosense Webster, Inc.
3333 Diamond Canyon Road
Diamond Bar, California 91765

Re: K001390
Biosense Webster Patient Cable and Leadwires
Regulatory Class: II (two)
Product Code: DSA
Dated: May 1, 2000
Received: May 2, 2000

Dear Ms. Ochoa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you

might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address: http.//www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular,
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

Indications for Use Statement

Abbreviated 510(k) No: K001390

Device Name: Biosense Webster Patient Cable and Leadwires

Indications For Use

The Biosense Webster Patient Cable and Leadwires System (consisting of a cable and leadwires) is intended to connect patient electrodes, placed on the patient body surface, to the CARTO and NOGA recording and mapping systems.

for Mark N Milhouse

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K001390